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## **Lilly Fraudulently Marketed Zyprexa, Montana Claims (Update5)**

By Margaret Cronin Fisk

March 12 (Bloomberg) -- Eli Lilly & Co. was sued by the state of Montana over claims the company fraudulently marketed its antipsychotic drug Zyprexa for unapproved uses and owes the state for prescription costs and harm to patients.

Lilly allegedly gave kickbacks to doctors and improperly promoted the drug to nursing homes as a sedative, Montana Attorney General Mike McGrath said in a complaint filed March 7 in state court in Helena. He claimed Lilly, the world's biggest maker of psychiatric drugs, bought off a "disgruntled" sales director to keep him from disclosing its marketing practices.

The drugmaker "instructed its representatives to minimize and misrepresent the dangers of Zyprexa, affirmatively and consciously placing company profits above the public safety," according to the complaint. "This failure to warn was designed and intended to maximize company profits."

Zyprexa has been linked to excessive weight gain and increased diabetes risk. The lawsuit is the seventh state claim against Indianapolis-based Lilly over Zyprexa marketing, and the second this year. Pennsylvania sued Lilly and two other makers of similar drugs Feb. 26 on behalf of its Medicaid programs. Both states seek unspecified reimbursement for money paid on prescriptions and any harm caused by Zyprexa.

### **Off-Label Marketing**

Lilly also faces federal probes into the drug's marketing. Lilly spokeswoman Marni Lemons said the company plans to fight the Montana suit and that it promotes its medications "only for approved uses," according to an e-mailed statement.

Lilly's off-label marketing has enabled Zyprexa, approved only for use for schizophrenia and bipolar disorder, to become the company's top-selling drug, Montana alleged in its complaint. Lilly promoted Zyprexa for use by patients suffering from dementia, depression and autism, among other non-approved uses, according to the court filing.

Under federal law, doctors can prescribe medications for uses that aren't approved by the U.S. Food and Drug Administration, although pharmaceutical companies are barred from marketing their drugs for such "off-label" uses.

Lilly created a 280-person sales force "to promote Zyprexa exclusively for off-label uses, specifically for long term care facilities to maximize off-label use of Zyprexa sales" for the elderly, Montana said in its complaint.

### **Johnson & Johnson, AstraZeneca**

"Lilly management participated, encouraged and authorized the unlawful payment of illegal kickbacks to physicians in order to continue generating sales of Zyprexa," the state claimed.

In addition to Zyprexa, AstraZeneca Plc's Seroquel and Johnson & Johnson's Risperdal, all members of a class of medications called atypical antipsychotics, have been linked to weight gain and diabetes. In September 2003, the FDA required the three companies to place warnings on the drugs' labels.

The three drugs, approved for schizophrenia and bipolar disorder, are among the top-selling medications

in the world. Lilly's global sales of Zyprexa were \$4.36 billion in 2006, Risperdal sales were \$4.18 billion and Seroquel's worldwide sales in 2006 were \$3.4 billion.

As many as half of the prescriptions for the three drugs are for off-label use, which has helped propel sales, according to market research data. U.S. Representative Henry Waxman, a California Democrat and chairman of the House Oversight and Government Reform Committee, last week asked the drugmakers to provide information on marketing practices for their antipsychotic medications.

#### Settled Cases

Lilly settled about 28,500 claims brought by users of Zyprexa for a total of as much as \$1.2 billion. About 1,300 individual claims remain pending, the company said in a regulatory filing last month.

The drugmaker also has been sued by Louisiana, West Virginia, Alaska, New Mexico and Mississippi, all seeking reimbursement of money spent on the drug by their Medicaid programs, as well as the costs of past and future medical care for any injuries caused by Zyprexa use. The Alaska suit against Lilly is set for trial in March 2008.

Most states didn't specify a dollar amount. West Virginia said it's seeking reimbursement of more than \$70 million it paid Lilly for Zyprexa. Any damages could be tripled under state law, according to the suit.

Louisiana also has sued New Brunswick, New Jersey-based Johnson & Johnson over Risperdal and Pennsylvania has sued both companies as well as London-based AstraZeneca last month.

The Montana suit also seeks reimbursement for patients who weren't on public assistance, said attorney Mike Miller, who represents the state. Under Montana law, the state attorney general can sue on behalf of all consumers, the lawyer said.

#### 'Treble Damages'

"We are looking for all funds spent by Montana or its citizens on Zyprexa since its launch in 1996, treble damages and attorneys' fees," Miller said.

Lilly rose 21 cents to \$52.80 at 4 p.m. in New York Stock Exchange composite trading.

Last week Lilly said it had sold \$2.5 billion of bonds to repay debt used in its acquisition of drugmaker Icos Corp., in its biggest bond sale ever.

Lilly's notes are rated Aa3 by Moody's Investors Service and AA by Standard & Poor's, both investment grade.

The lawsuit is Montana v. Eli Lilly & Co., No. ADV-2007-188, 1st Judicial District Court, Lewis & Clark County, Montana.

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